

-8

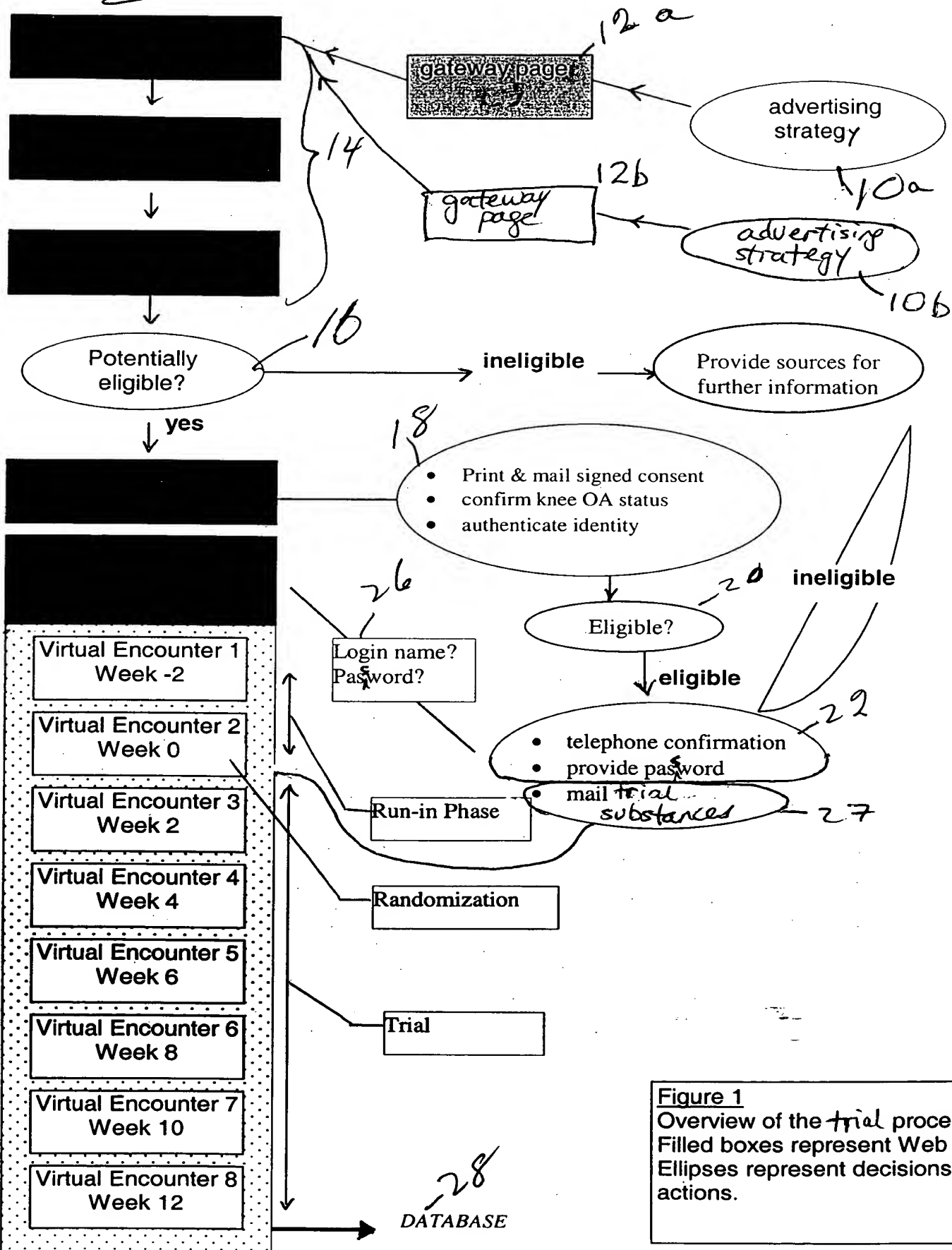


Figure 1
 Overview of the trial process.
 Filled boxes represent Web pages.
 Ellipses represent decisions and actions.

New Subject Applying (Detailed Workflow)

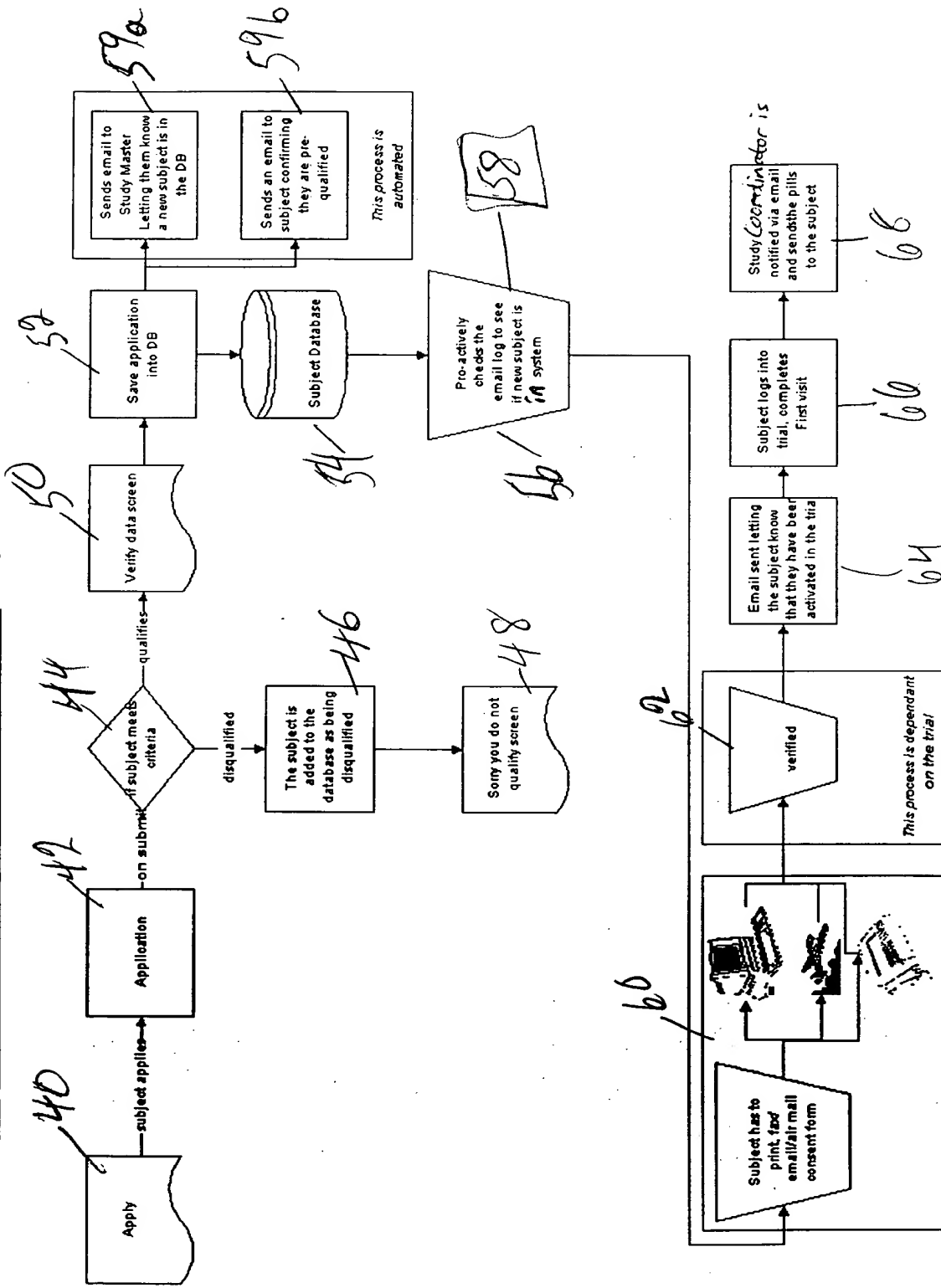


Fig. 2

Overall Site Information flow

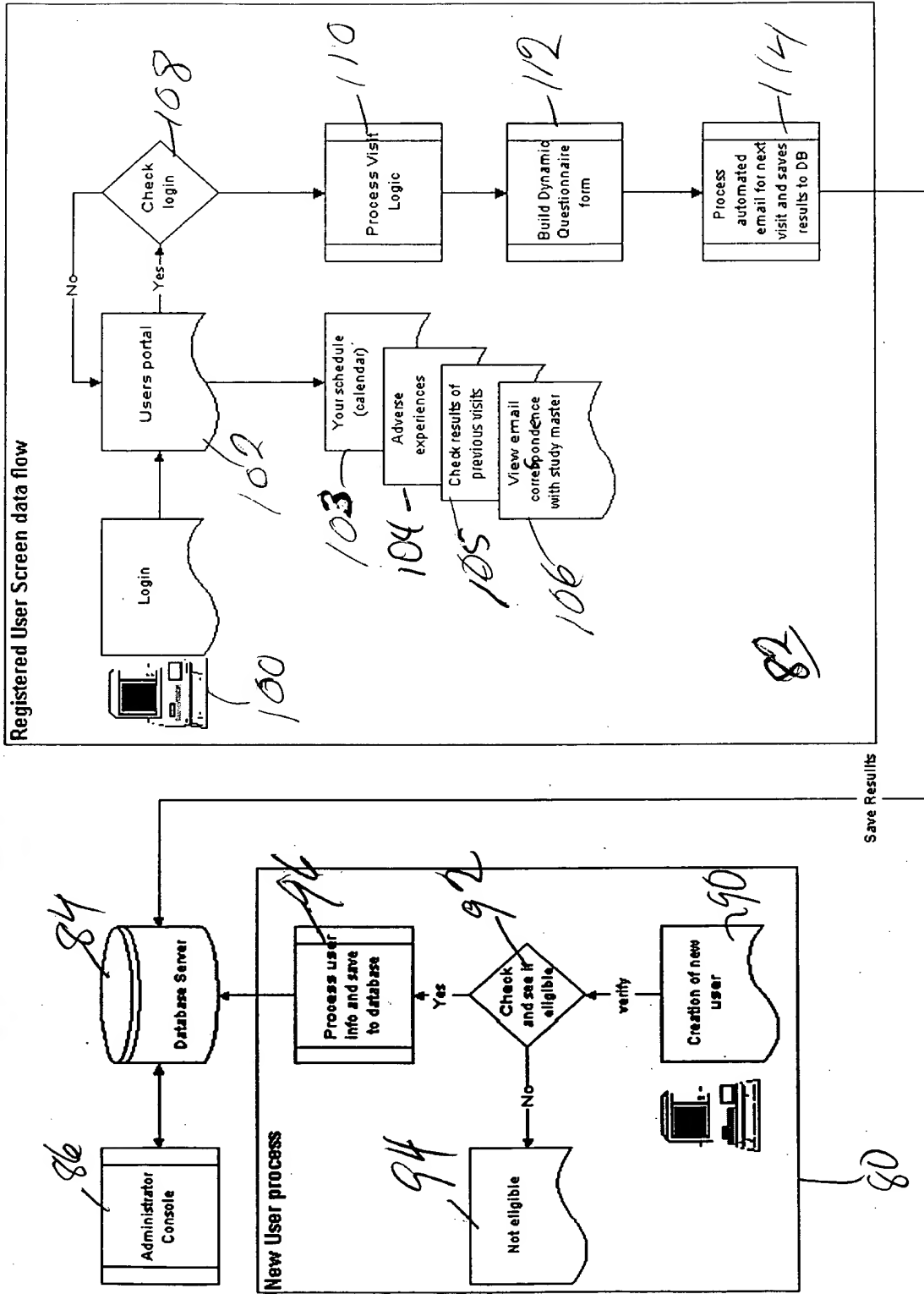


Fig. 3

Proc ss Visit Logic

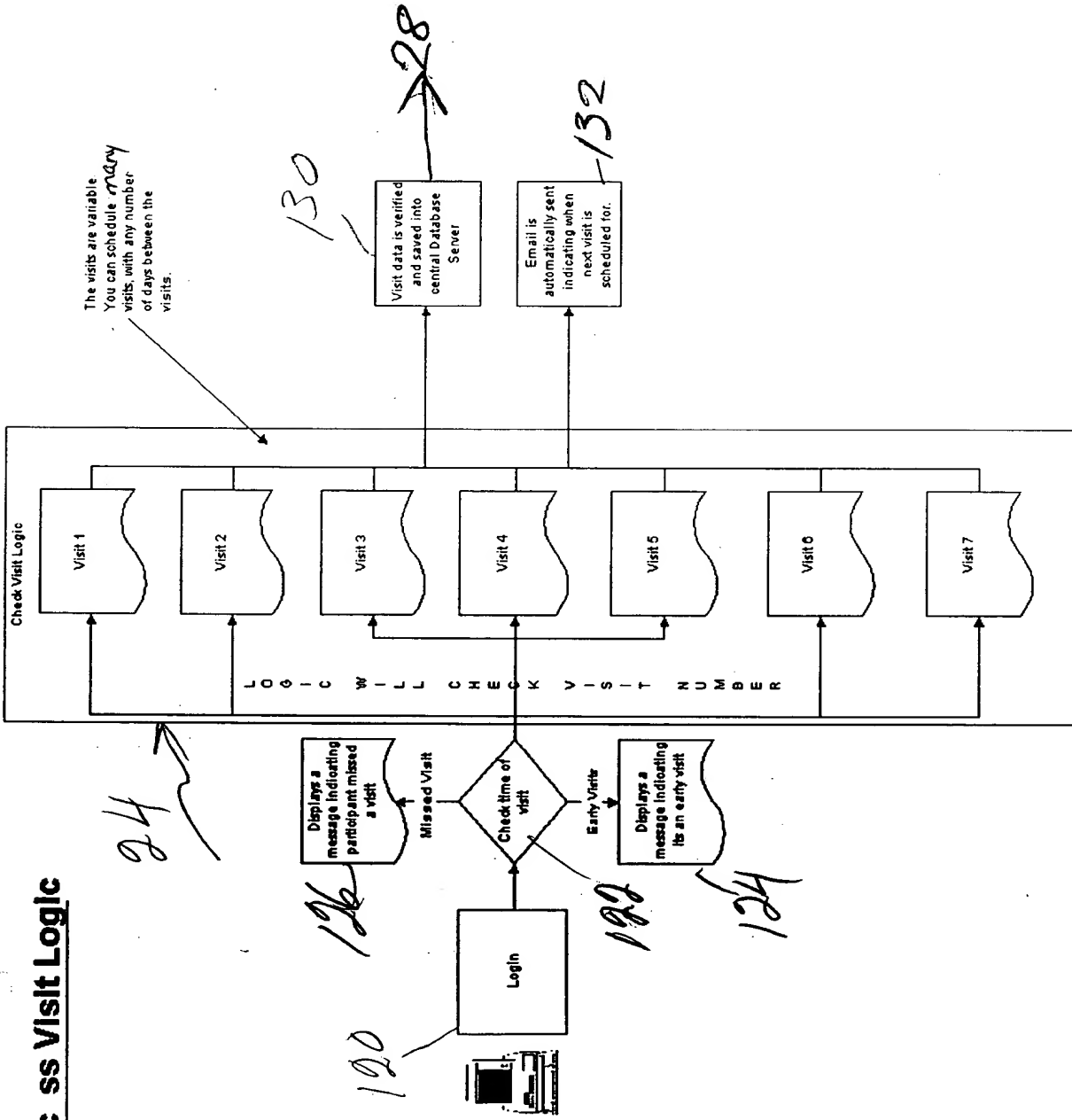


Fig. 4

Subjects Functions

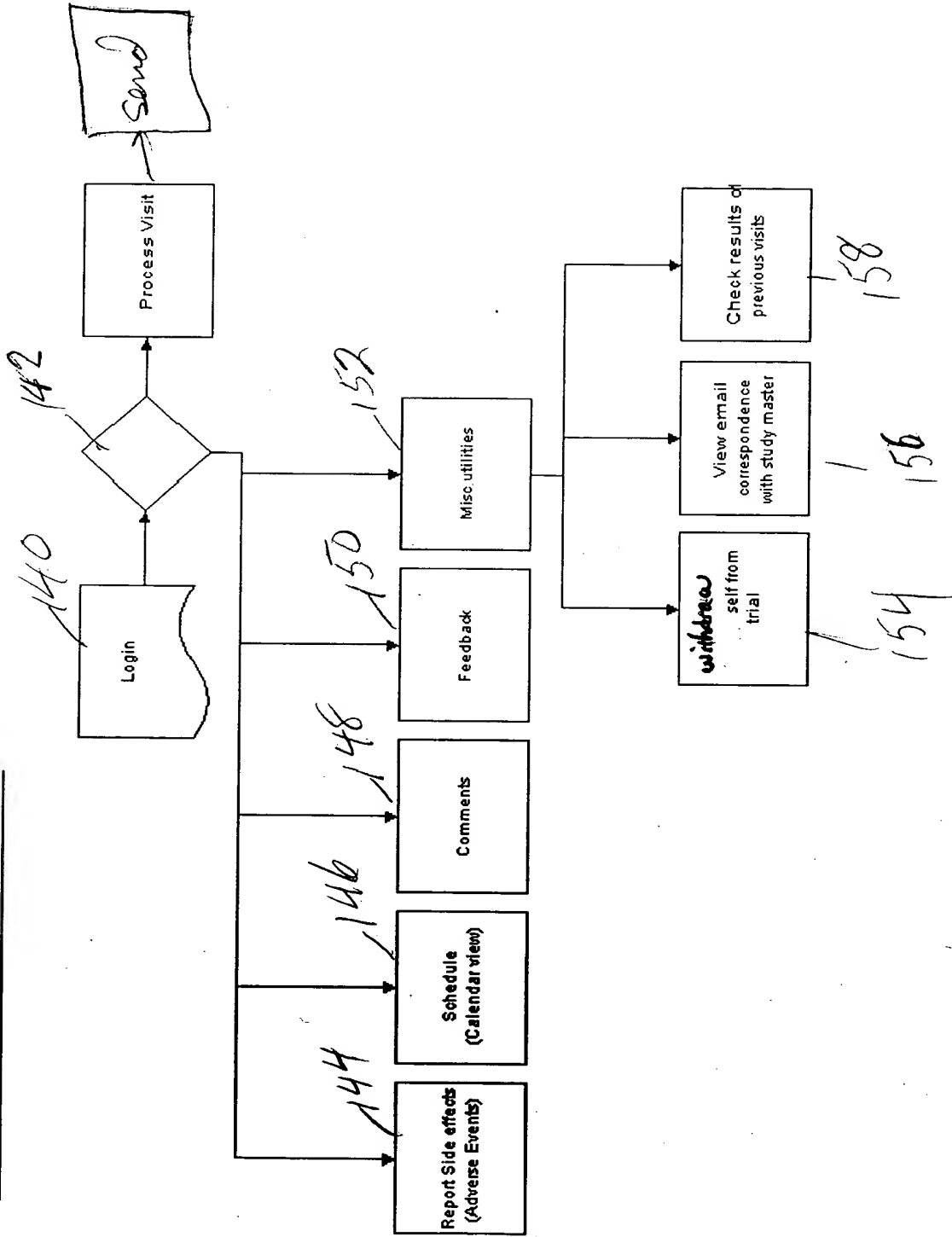


Fig. 5

Admin Functions (console)

This section is only accessed by study master

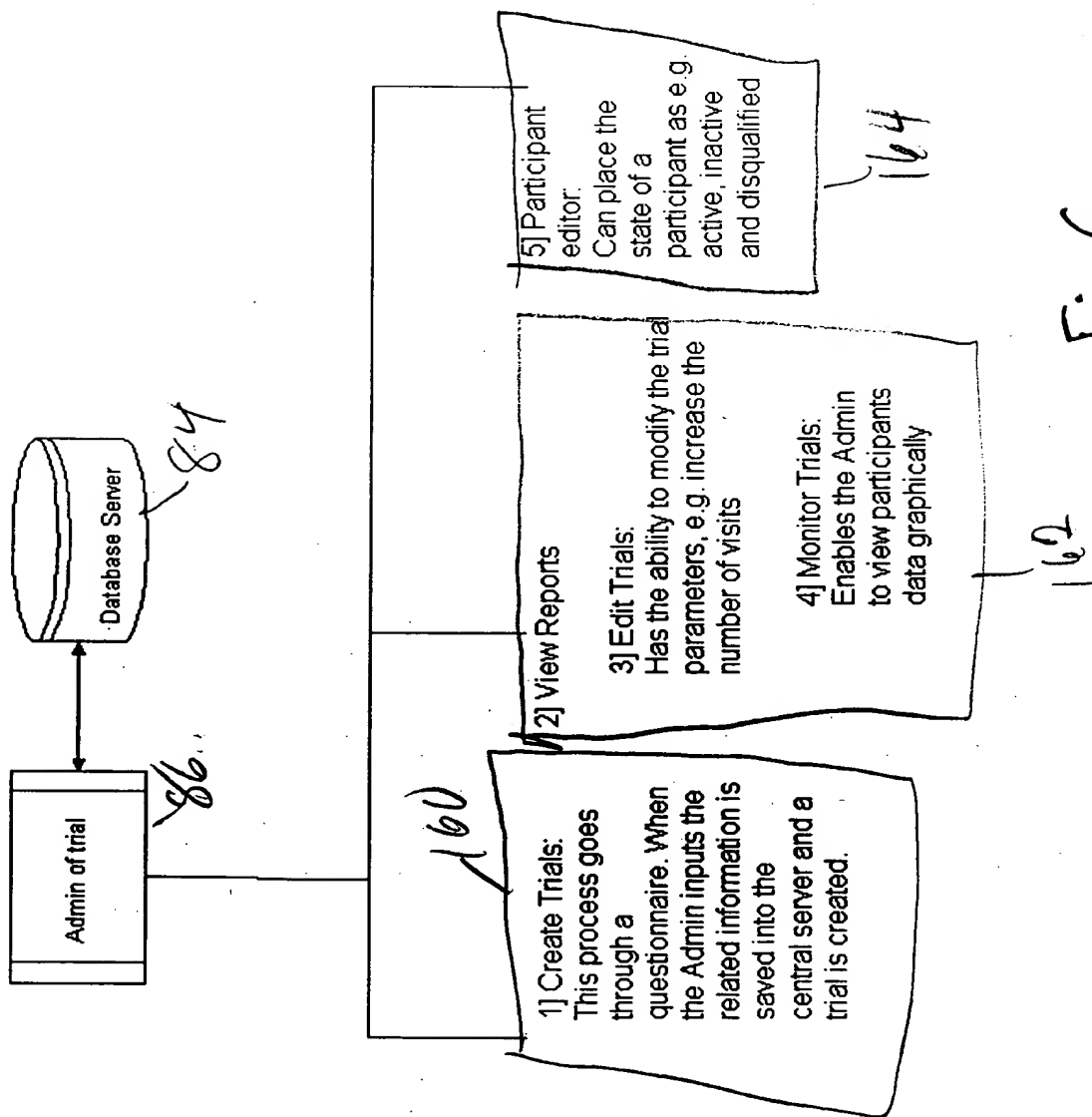


Fig 6

Database Design

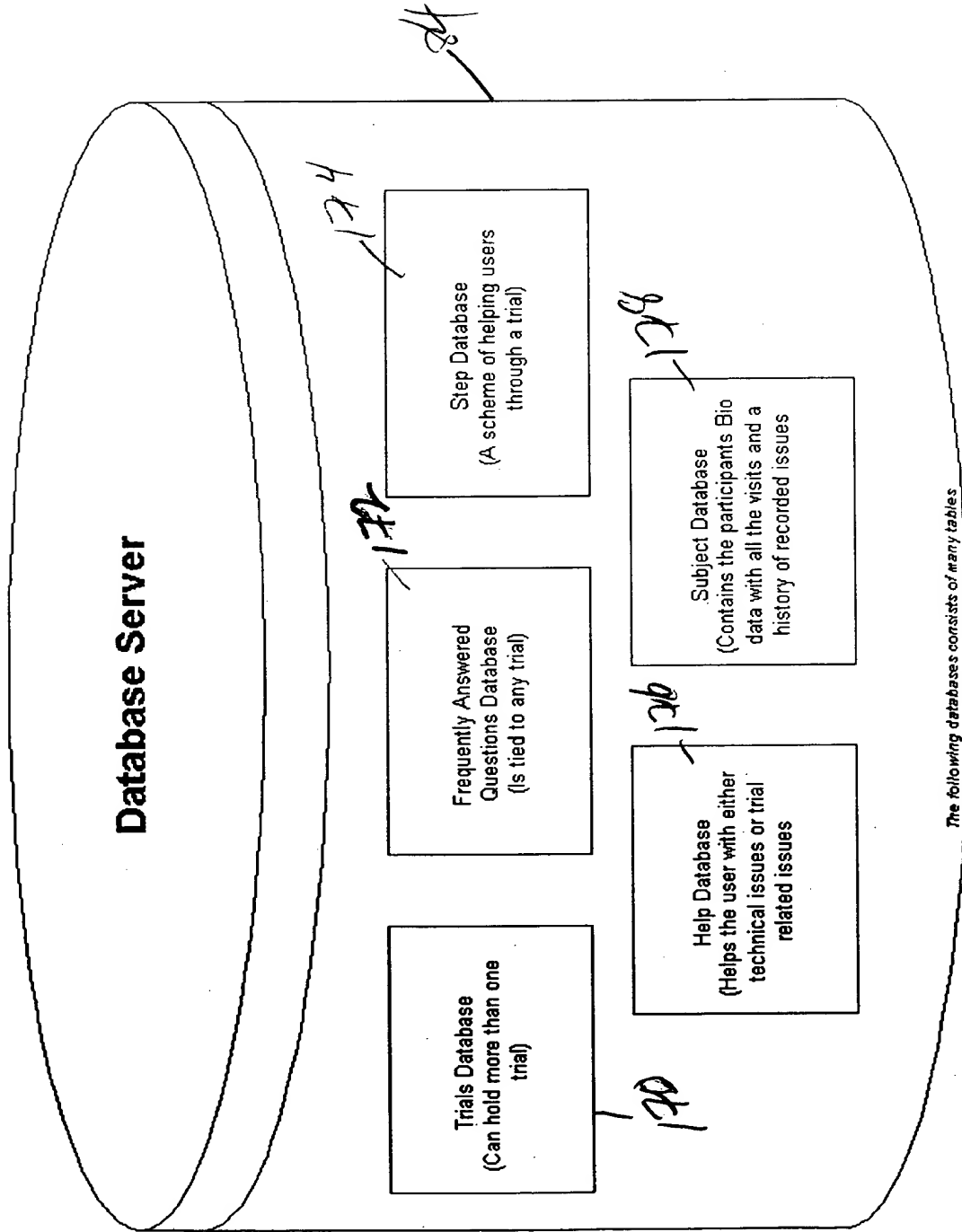


Fig. 7

ONLINE VISITS

YOUR SCHEDULE

REPORT
SIDE-EFFECTS

QUESTIONS?

COMMENTS?

LOGOUT

Welcome to your First Visit**SECTION A:**

The following questions concern the amount of **pain** you have experienced due to arthritis in your knee(s). For each situation please enter the amount of pain experienced in the last 48hrs.

QUESTION: How much pain do you have?

1. Walking on a flat surface	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Going up or down stairs.	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. At night while in bed?	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Sitting or lying?	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Standing upright?	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

SECTION B:

The following questions concern the amount of **joint stiffness** (not pain) you have experienced in the last 48 hours in your knee(s). Stiffness is a sensation of restriction or slowness in the ease with which you move your joints.

QUESTION: How severe is your stiffness?

6. After first waking in the morning?	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. After sitting, lying or resting later in the day?	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Fig. 8A

SECTION C:

The following questions concern your **physical functions**. By this we mean your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last 48 hours due to arthritis in your knee(s).

QUESTION: What degree of difficulty do you have?

8. Going down the stairs?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

9. Going up the stairs?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

10. Rising from sitting?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

11. Standing?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

12. Bending to the floor?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

13. Walking on a flat surface?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

14. Getting in/out of a car?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

15. Going shopping?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

16. Putting on socks/stockings?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

17. Rising from bed?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

18. Taking off socks/stockings?

None

Mild

Moderate

Severe

Extreme

☐☐☐☐☐

Fig. 8B

None Mild Moderate Severe Extreme

19. Lying in bed?

None Mild Moderate Severe Extreme

20. Getting in/out of the bath?

None Mild Moderate Severe Extreme

21. Sitting?

None Mild Moderate Severe Extreme

22. Getting on/off toilet?

None Mild Moderate Severe Extreme

23. Doing heavy domestic duties?

None Mild Moderate Severe Extreme

24. Doing light domestic duties?

None Mild Moderate Severe Extreme

Important:

1. You may take your usual painkillers for your knees if you need them. However, we need you to keep a record of how many painkillers you take each day. We will ask you for this number at each of your visits.
2. Also, we ask that you **stick to the same painkiller** for the length of the study.

Please enter the name of the painkiller that you usually take for your knee-pain (eg ibuprofen, Motrin, Tylenol):

This is the painkiller that we will expect you to use during the study for breakthrough pain

Please enter your current height (feet and inches)

4 0

Please enter your current weight (pounds)

0

Submit Clear

Fig. 8C

11/11/

ONLINE VISITS

YOUR SCHEDULE

REPORT
SIDE-EFFECTS

QUESTIONS?

COMMENTS?

LOGOUT

Welcome to your Second Visit

The following questions concern the amount of pain you have experienced due to arthritis in your study joint(s). For each situation please enter the amount of pain experienced in the last 48hrs.

FIG. 9

QUESTION: How much pain do you have?

1. Walking on a flat surface	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Going up or down stairs.	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. At night while in bed?	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Sitting or lying?	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Standing upright?	None	Mild	Moderate	Severe	Extreme
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Other questions:

6. How many cigarettes do you smoke on average each day?
- ☒ None
- ☐ Less than 5 per day
- ☐ 4-14 per day
- ☐ 15-24 per day
- ☐ 25 or more per day
7. How many alcoholic beverages do you drink on average each week?
- ☒ None
- ☐ Less than 1
- ☐ 1-3
- ☐ 4-6
- ☐ 7-13
- ☐ 14-20
- ☐ 21 or more
8. Please tell us how many of your usual painkillers you have taken since your last completed visit.

Submit Cancel

Fig. 9